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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,066	04/28/2005	Keiji Iwamoto	63286(46342)	5897

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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,066	IWAMOTO ET AL.	
	Examiner	Art Unit	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 September 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/03/2008 has been entered.

Status of Application, Amendments and/or Claims

The amendment of 03 September 2008 has been entered in full. Claims 1-21 and 23-48 have been cancelled. Claims 22 and 49 have been amended.

Claims 22 and 49 are under examination.

Drawings

The drawings for figure 3 filed 09/03/2008 has been accepted.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: A method of screening a compound using SGLT.

Rejections Withdrawn

35 USC § 112, First paragraph (Written Description)

Applicant's response and amendments made to claim 22 filed on 09/03/2008 have overcome the rejection of claims 22 and 49 under 35 USC 112, First paragraph. Claim 22 no

long recites "having at least about 90% homology to the amino acid sequence". The rejection of claims 22 and 49 under 35 USC 112, First paragraph has been withdrawn.

35 USC § 112, First paragraph (Enablement)

Applicant's response and amendments made to claim 22 filed on 09/03/2008 have overcome the rejection of claims 22 and 49 under 35 USC 112, First paragraph. Claim 22 no long recites "having at least about 90% homology to the amino acid sequence". The rejection of claims 22 and 49 under 35 USC 112, First paragraph has been withdrawn.

35 USC § 112, Second paragraph

Applicant's response and amendments made to claim 22 filed on 09/03/2008 have overcome the rejection of claims 22 and 49 under 35 USC 112, Second paragraph. Claim 22 no long recites "a cell capable of producing the homolog", "a mixture of cell", "cases". In addition, Applicants have added a step relating back to the preamble in claim 22 and have amended claim 49 to clarify how the measurements for the accumulation of glucose analogs are determined in the claimed method. The rejection of claims 22 and 49 under 35 USC 112, Second paragraph has been withdrawn.

35 USC § 102

Applicant's response and arguments filed on 09/03/2008 have overcome the rejection of claims 22 and 49 under 35 USC 102(b). The references by Iwamoto et al. and Thornton et al. doe not teach the new added limitation reciting "the cell is present in a jejunal slice in an

intestinal organ culture system." The rejection of claims 22 and 49 under 35 USC 102(b) has been withdrawn.

New Ground of Rejection

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is indefinite because it is not clear how the proteins SGLT homologs can form 'salts thereof".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwamoto et al. in view of Bosc et al. (1998, Peptides Volume 19, Issue 7, pages 1249-1253).

The claimed invention is drawn to a method of screening a compound or its salt that regulates the glucose uptake activity of a Na+/glucose transporter (SGLT) homolog in the small intestine, which comprises: determining (i) the glucose uptake activity of a cell expressing the homolog in the absence of a test compound and (ii) the glucose uptake activity expressing the homolog and in the presence of a test compound, wherein the cell is present in a jejunal slice in an intestinal organ culture system, and comparing the glucose uptake activities and selecting a test compound that promotes or inhibits the glucose uptake activity, wherein the homolog is a protein which comprises the amino acid sequence by of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 5 or SEQ ID NO: 50, and has an active glucose transport activity, or a salt thereof. In addition, in the claimed method the glucose uptake activities are determined by measuring the amount of accumulated glucose analogs, which are labeled with radioactivity, accumulated in the cells, by counting the radioactivity, and comparing them as an indicator of the active transport activity of glucose.

Iwamoto et al., (2002) teach a method of screening a compound regulating glucose uptake activity using the homolog (page 36, lines 19-29) comprising SEQ ID NO:1 (abstract page 1 and page 1 of sequence listing), which has 100% homology with SEQ ID NO:1 of instant application. In addition, Iwamoto et al. (2002) teach a method of screening for the compound

comprising comparing (i) glucose uptake activity in cells having the ability of producing the protein and (ii) glucose uptake activity in cells having the ability of producing the protein in the presence of the test compound (page 36, lines 15-30). Finally, Iwamoto et al. (2002) teach that the glucose activity of the method is determined by measuring radioactivity of the intracellular accumulation of [3H]-labeled glucose or glucose analogs, such as 2-deoxy-glucose (page 36, lines 23-30). However, Iwamoto et al. does not teach that the cell expressing a SGLT homolog is present in a jejunal slice in an intestinal organ culture system.

Bosc et al. (1997) teach a method of screening a compound using a tissue isolated from the jejunum from the small intestine as an intestinal organ culture system (page 1250, left column, 5th paragraph, Figure 1, page 1251).

Thus, it would be have been obvious for one skilled in the art to have modified the screening method of Iwamoto et al. by using the jujenum tissue from the small intestine as taught by Bosc et al. One of ordinary skill in the art at the time the invention was made would been motivated to use cells from the jejunum tissue because this intestinal organ culture system is a well known organ culture system to study glucose transport activity of SGLT-1 and has been successful in identifying inhibitors of SGLT1. In addition, one of ordinary skill in the art at the time the invention was made would been motivated to use cells from jejunum tissue as an intestinal organ culture system because "a person of ordinary skill has good reason to pursue the know options within is or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." Accordingly, the invention taken as a whole is prima facie obvious.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
September 18, 2008

/Robert Landsman/
Primary Examiner, Art Unit 1647